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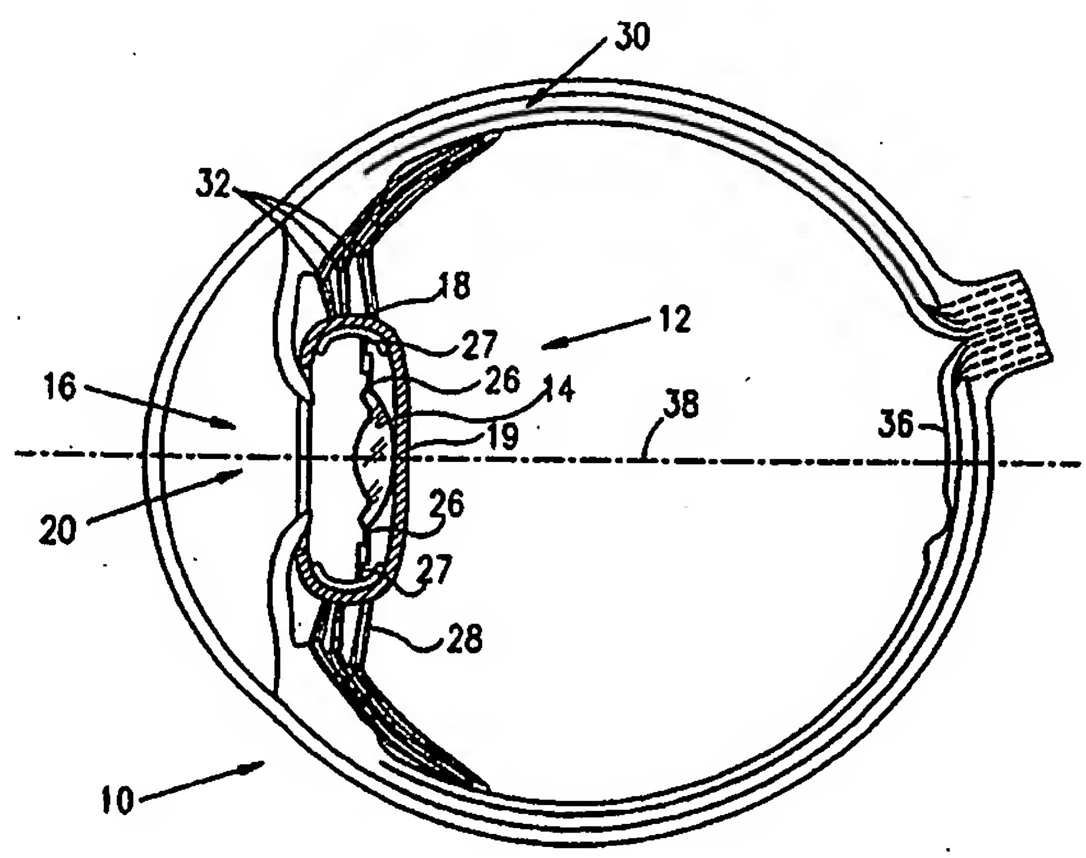

(57) Abstract

The present invention is directed to an intraocular lens system (12) installed in place of a removed natural lens, and inserted within the original lens capsule (16). Intraocular lens system (12) includes an optic (14), arms (22) pivotally attached thereto at pivots (26, 27), and an expanding ring (24). The ciliary muscles (34) act through zonule fibers (28) to push on the capsule (16), and move the optic (14) on the intraocular lens system (12).

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INTRAOCULAR LENS ASSEMBLY

FIELD OF THE INVENTION

The present invention relates generally to intraocular lens assemblies for implantation into the human eye and more particularly to intraocular lens assemblies which provide accommodation in response to the contraction and relaxation of the ciliary muscles of the eye.

BACKGROUND OF THE INVENTION

Various types of intraocular lens implants are known. A particularly advantageous accommodating intraocular lens implant is described and claimed in applicant's published PCT patent application WO 96/15734, the contents of which are hereby incorporated by reference. This published PCT patent application, including specifically the discussion in the Background section thereof, as well as European Patents EP 478929 and 592813, Published European Patent Applications EPA 0507292; EPA 0337390; EPA 0478929; EPA 0592813 and the following U.S. Patents are believed to represent the state of the art in the patent literature: 5,593,436; 5,578,082; 5,496,366; 5,476,514; 5,366,501; 5,275,624; 5,275,623; 5,152,789; 4,994,082; 4,963,148; 4,902,293; 4,892,543; 4,888,012; 4,842,601; 4,790,847; 4,575,373; 4,464,448; 4,463,458; 4,426,741; 4,409,691; 4,254,509; 4,253,199.

Reference is also made to the following publications in the non-patent literature:

Ronald A. Schachar, CAUSE AND TREATMENT OF PRESBYOPIA WITH A METHOD FOR INCREASING THE AMPLITUDE OF ACCOMMODATION, Ann. Ophthal. 1992; 24:445-452;

Ronald A. Schachar et al, EXPERIMENTAL SUPPORT FOR SCHACHAR'S HYPOTHESIS OF ACCOMMODATION, Ann. Ophthal. 1993; 25:404-409;

Ronald A. Schachar et al, A PHYSICAL MODEL DEMONSTRATING SCHACHAR'S HYPOTHESIS OF ACCOMMODATION, Ann. Ophthal. 1994; 26:409;

D.A. Grinberg, QUESTIONING OUR CLASSICAL UNDERSTANDING OF ACCOMMODATION AND PRESBYOPIA, American Journal of Optometry & Physiological Optics, Vol. 63, No. 7, pp. 571 - 580.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved intraocular lens assembly.

There is thus provided in accordance with a preferred embodiment of the present invention an intraocular lens assembly for implantation in a human eye, the eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly including:

an optic having anterior and posterior surfaces;

at least two articulated linkage arms, each being attached to the optic at a first position on the arm thereof and cooperating with the ciliary muscle or the zonules at a second position on the arm, the optic being integrally formed as a single piece together with the at least two articulated linkage arms.

Further in accordance with a preferred embodiment of the present invention the intraocular lens assembly also comprises a ring attached to the at least two articulated linkage arms and integrally formed therewith as a single piece.

In one group of embodiments of the present invention, an intraocular lens assembly incorporates an optic for implantation within the lens capsule of the eye, the optic being held in place by at least two substantially rigid linkage arms, or haptics, which are attached at their inner ends to the edge or face of the optic. The outer ends of the linkage arms are coupled with the movement of the zonules and the ciliary muscle. The optic, linkage arms and connecting parts are made of biologically inert plastic or other biologically inert materials.

In this group of embodiments, the linkage arms are connected to pivot joints at one or both the inner and outer ends thereof, which permit the arms to rotate about the pivot axes in response to radial expansion or contraction of the equatorial diameter of the capsule. When the ciliary muscle of the eye is relaxed, for distance vision, the arms hold the optic in a position which focuses distant images onto the retina. When

the ciliary muscle contracts to accommodate for near vision, the equatorial diameter of the lens capsule changes, exerting force on the outer ends of the linkage arms and thereby causing them to rotate about their pivots and shift the optic forward, away from the retina, so as to focus near images onto the retina. When the ciliary muscle again relaxes, the linkage arms move in the opposite direction, returning the optic to its previous position of distant focus.

It may be appreciated that the equatorial diameter of the lens capsule is determined at any time by the balance of outward radial force exerted by the zonular fibers and inward force due to the natural elasticity of the lens capsule. Furthermore, the portions of the lens capsule remaining after surgery, particularly the posterior wall of the lens capsule, provide, in some embodiments of the invention, a force which (axially) biases the optic toward the front of the eye. Further embodiments of the invention provide other elements for exerting forces which may affect the balance of forces acting on the optic and change its axial position.

In some preferred embodiments of the present invention, the outer ends of the linkage arms are held in contact with or attached to an expanding ring, which is itself in contact with the edges of the lens capsule adjacent to the zonules. The expanding ring serves both to hold the capsule open (i.e., to prevent its axial collapse) and to couple the linkage arms to the motion of the zonules. This expanding ring may also exert an additional outward radial force on the equatorial edge of the capsule or may be segmented so that it serves only to position the linkage arms and to hold the lens capsule open.

Further embodiments of the invention incorporate two or more springs or other tensile members attached at one of their respective ends to the ciliary muscle, zonules or expanding ring at symmetrically spaced points surrounding the capsule of the eye. The other ends of the springs are either fastened together centrally or attached to the ciliary muscle, zonules or expanding ring in such a way as to cause an inward radial force to be exerted on the equatorial edge of the capsule. For example, such tensile members may take the form of a tensioned ring attached along the periphery of the lens capsule. This type of tensile member effectively reinforces the inherent tension of the

edge of the lens capsule itself. Such tensioned members are especially useful when the posterior wall of the lens capsule is also removed.

The ciliary muscle or zonules produce a contrary force in the outward axial direction. Outward radial motion of the zonules or ciliary muscle will stretch the springs, increasing the forward axial force and causing the optic to move forward in the capsule. When the zonules or ciliary muscle subsequently return radially inward, the linkage arms will force the optic back to its previous position.

In general, the lens capsule itself performs a similar function, in a somewhat different manner. The elasticity of the capsule, especially when the capsule is held open by the expanding ring, exerts an inward force on the edge of the lens capsule, where it is attached to the zonules. The posterior wall of the lens capsule performs an additional function in many embodiments of the invention, in that in these embodiments the optic is in contact with the posterior wall of the lens capsule. Under this condition, the posterior wall acts on the optic to provide a restoring force for the optic when the diameter of the lens capsule increases. In this way it is not necessary to attach the outer edge of the haptics to the expanding ring to provide movement of the optic when the diameter of the lens capsule is increased.

In a preferred embodiment of the invention, in accordance with Schachar's theory of accommodation, the optic is positioned initially, for distant vision, in contact with the posterior wall of the capsule of the eye. Two or more linkage arms, made of rigid plastic or other rigid material, are coupled flexibly to the optic so as to permit the linkage arms to pivot at the coupling during motion of the linkage arm, while still transmitting full axial motion from the arm to the optic. The outer ends of the linkage arms are likewise preferably flexibly attached to an expanding ring, which holds them in place at the edge of the capsule adjacent to the zonules.

According to Schachar's theory, when the eye accommodates for near vision, contraction of the zonules exerts an outward radial force, which causes the equatorial diameter of the lens capsule to increase. Consequent expansion of the expanding ring causes the arms to rotate in their respective pivot joints on the expanding ring and on the optic, thereby causing the optic to move axially forward in the capsule. The linkage arms are geometrically constructed in such a way that a small change in the

equatorial diameter of the capsule will cause a larger change in optic position, sufficient to provide for focus of near images onto the retina.

An alternative preferred embodiment of the invention is similar to the embodiment described above, but is designed to operate in accordance with Helmholtz's theory. In this alternate embodiment the optic is coupled to the expanding ring by two or more linkage mechanisms, each of which comprises an inner arm and an outer arm. The inner arm is preferably rigidly connected at its inner end to the optic, and by a pivot at its outer end to the inner end of the outer arm. The outer arm is connected at its outer end to the expanding ring. When the ciliary muscle contracts for near vision accommodation, according to Helmholtz, the elasticity of the lens capsule causes the capsule's equatorial diameter to decrease and forces the expanding ring to contract. This contraction causes the outer arms to rotate about their pivots in such a way that the angle between the inner and outer arms at the pivot connecting them decreases. The inner and outer arms are so arranged that this rotation and decrease in pivot angle will cause the optic to move axially forward, thus providing for near images to be focused onto the retina.

In accordance with preferred embodiments of the present invention, flexible, resilient linkage arms may be radially pre-loaded, for example by the pressure of the posterior wall of the lens capsule on the optic, so as to hold the intra-optic assembly in place without their connection to an expanding ring.

In other preferred embodiments of the invention, the outer ends of the linkage arms, whether rigid or flexible, may be fastened directly or indirectly to the zonules, ciliary muscle or radial edge of the lens capsule by suturing or gluing. It may be appreciated that the various types of mechanical linkages described here in relation to the various preferred embodiments of the invention may be used alternatively in conjunction with an expanding ring or with other methods, described herein, of coupling the linkage arms to the motion of the zonules or ciliary muscle.

In some preferred embodiments of the invention, the linkage arms or haptics are constructed of either rigid or resilient material, and are coupled to the edge of the capsule adjacent to the zonules, preferably by an expanding ring. A substantially rigid ring is connected by a pivot to each of the linkage arms at a point between the arm's outer end and its inner pivot connection to the optic. The substantially rigid ring has a

diameter smaller than the minimum equatorial diameter of the capsule, but larger than the optic and generally coaxial to it. The pivots on the rigid ring serve as fulcrums, and the linkage arms act as levers, rotating about the fulcrums when the capsule's equatorial diameter changes. In accordance with Schachar's theory, the linkage arms may be constructed so that when the equatorial diameter of the capsule increases, said lever action will cause the optic to move forward.

An alternative embodiment of the invention, in accordance with Helmholtz's theory, similarly includes rigid or resilient linkage arms, connected to a rigid ring with pivots acting as fulcrums for lever action of the arms, as in the preceding embodiment. In this alternative embodiment, however, the linkage arms are constructed so that when the equatorial diameter of the capsule decreases, said lever action will cause the optic to move forward.

In a further preferred embodiment of the invention, two optics are used, one of which is adjacent to the posterior wall of the lens capsule and the other is held parallel and anterior to it, with an intervening space between them. The refractive power of the optics and the spacing between them is so designed that when the ciliary muscle is relaxed, distant objects are focused onto the retina. Each optic is held in place by two or more linkage arms or haptics, which are shaped and positioned in such a way as to cause each of the arms of the anterior optic to come into contact with and cross a corresponding arm of the posterior optic, at a pivot point along or near the equatorial plane of the capsule.

These points of contact of the corresponding anterior and posterior linkage arms are located at a radius from the center of the capsule that is greater than the radii of the two optics but smaller than the total equatorial radius. The outer ends of the arms are flexibly anchored to an expanding ring at the edge of the lens capsule, adjacent to the zonules. When the ciliary muscle contracts and the equatorial diameter of the capsule decreases, in accordance with Helmholtz's theory, the angle of crossing between the corresponding anterior and posterior linkage arms increases in a scissors-like action, which in turn increases the spacing distance between the anterior and posterior optics. As this spacing increases, the laws of optics provide that the refractive power of the lens couple will decrease, thereby allowing near objects to be focused onto the retina. Similar

embodiments, utilizing the same principles can be applied to design of lens couples which operate according to the Schachar theory.

There is also provided, in accordance with a preferred embodiment of the invention an intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly comprising:

an optic having anterior and posterior surfaces depending from a common edge;

at least two linkage arms, integrally formed as one piece with said optic, each linkage arm being attached to the optic at a first position on the arm thereof and cooperating with ciliary muscle or the zonules at a second position on the arm; and

at least two pivots, one of which is rotatably attached to each respective linkage arm intermediate the first and second positions.

There is further provided, in accordance with a preferred embodiment of the invention, an intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly comprising:

an optic having anterior and posterior surfaces depending from a common edge; and

at least two substantially rigid linkage arms integrally formed as one piece with said optic, each being attached to the optic at a first position on the arm thereof and cooperating with ciliary muscle or the zonules at a second position on the arm.

There is further provided, in accordance with a preferred embodiment of the invention, an intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle and at least a portion of a lens capsule including an edge thereof and at least a portion of a posterior wall thereof, the assembly comprising:

an expanding ring associated with the edge which contacts the edge portion of the lens capsule and preferably the posterior wall and positions the posterior wall toward the back of the eye from center of the lens capsule; and

an optic associated with the expanding ring and integrally formed therewith.

There is further provided, in accordance with a preferred embodiment of the invention, an intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle and at least a portion of a lens capsule including an edge thereof, the assembly comprising:

an expanding ring associated with the edge portion of the lens capsule and which provides a resilient radial force on the edge; and

an optic associated with the expanding ring and integrally formed therewith.

Preferably, the expanding ring bears against the edge of the lens capsule and provides an outward radial force or is attached to the edge and provides an inward radial force.

There is further provided, in accordance with a preferred embodiment of the invention, an intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle and at least a portion of a lens capsule including an edge thereof and at least a portion of a posterior wall thereof, the assembly comprising:

an expanding ring associated with the edge comprising alternating rigid and elastic portions; and

an optic associated with the expanding ring and integrally formed therewith.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to better understand the invention and to see how it may be carried out in practice, some preferred embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a cross-sectional view of an eye having therein a lens capsule containing an intraocular lens assembly according to a preferred embodiment of the invention;

Figs. 2A and 2B are front and sectional side views of a preferred embodiment of the intraocular lens assembly shown in Fig. 1, Fig. 2B being taken along lines 2B - 2B of Fig. 2A;

Figs. 3A and 3B are respective sectional elevations of a preferred embodiment of the invention showing relative displacement of an optic forming an integral part of the intraocular lens assembly;

Figs. 3C and 3D are respective sectional elevations of another preferred embodiment of the invention showing relative displacement of an optic forming an integral part of the intraocular lens assembly;

Fig. 4 shows a cross-sectional view of an eye having therein a lens capsule containing an intraocular lens assembly according to another preferred embodiment of the invention;

Figs. 5A and 5B are front and partial side views of a preferred embodiment of the intraocular lens assembly shown in Fig. 4, Fig. 5B being taken along lines 5B - 5B of Fig. 5A;

Figs. 6A and 6B are respective sectional elevations of a preferred embodiment of the invention showing relative displacement of an optic forming an integral part of the intraocular lens assembly;

Figs. 6C and 6D are respective sectional elevations of another preferred embodiment of the invention showing relative displacement of an optic forming an integral part of the intraocular lens assembly; and

Fig. 6E is a sectional elevation showing part of the apparatus of Figs. 6C and 6D and illustrating the angular and geometric relationship between various portions thereof.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 shows a cross-section of a human eye 10 having an adaptive intraocular lens system 12, in accordance with a preferred embodiment of the invention, installed in place of the original material in a lens capsule 16. In this and all other cross-sectional diagrams of the eye and structures therein, the cornea and other anterior portions of the eye are at the left of the figure, and the retina and posterior portions of the eye are to the right.

Intraocular lens system 12 comprises an optic 14 placed within lens capsule 16. Lens capsule 16, from which the original lens material has been removed,

includes an outer edge 18, which is left intact and, optionally, a posterior wall 19 at least a portion of which may be left intact. At least a portion of the original anterior wall of the capsule is generally removed during the operation for removal of the lens material leaving an opening 20, through which the lens system is installed.

As shown more clearly in Figs. 2A and 2B, intraocular lens system 12 also includes two or more linkage arms 22, also known as haptics, which are integrally formed as one piece with the optic 14 at one end of the arms and which preferably rest on or are pivotably attached to an expanding ring 24 at a second end thereof.

In a preferred embodiment of the invention shown in Figs. 1 - 2B, arms 22 are pivotably attached for limited rotational motion at pivots 26, symmetrically placed on the outer edge of the optic 14, and at pivots 27 on expanding ring 24. In accordance with a preferred embodiment of the present invention, pivots 26 and 27 are defined by flexible sections of the integrally formed one-piece intraocular lens system.

As shown in Fig. 1, one end of zonular fibers 28, also known as zonules, is attached to edge 18 of lens capsule 16. The other end of the zonules is attached to the sclera 30 of the eye. Intermediate their ends, the zonular fibers are acted upon by ligaments or the like 32 which are controlled by ciliary muscle 34. The portion of the eye comprising the ciliary muscle and the volume it encloses is also known as the ciliary body.

Optic 14 produces an image on the retina at the back of the eye 10 corresponding to a focal plane 36. In order to provide accommodation, optic 14 is made capable of movement along optical axis 38. As in the normal eye, accommodation is made consequent to changes in tension of the zonular fibers. This change in tension acts on optic 14 so as to alter the image distance from optic 14 to focal plane 36.

In the preferred embodiment shown in Figs. 2A and 2B, linkage arms 22 each include a central beam portion 40, which is relatively rigid, having formed onto opposite ends thereof pivots 26 and 27. In contrast to the prior art, which employs different materials for the optic and the arms 22, the present invention may employ the same material for optic 14 and for arms 22, including the beam portion 40 and the pivots 26 and 27, wherein the relative rigidity of each portion is determined by its thickness.

Alternatively the intraocular lens system may be formed as one piece from plural materials or reinforced, so as to cause various portions thereof to have greater or lesser rigidity.

The pivots 26 and 27 may be made of flexible material, which allows twisting or rotation of the arms about the pivot in response to rotational force applied to the arms 22, but prevents substantial axial motion of the arms. This flexible material may also be elastic, so that pivots 26 and 27 exert a biasing force on arms 22, which will tend to return optic 14 to its original position when the rotational force applied to the arms is removed.

Expanding ring 24 is constructed preferably so as to exert an outward radial force, which will cause the ring to conform to the edge 18 of lens capsule 16, and expand or contract in response to expansion or contraction of the capsule, respectively. Ring 24 serves to couple the outer end of linkage arms 22 to edge 18, so that radial forces exerted by zonules 28 and ciliary muscle 34 can act upon said arms. Ring 24 may further serve to open capsule 16, i.e. to separate the anterior and posterior portions of the lens capsule, in place of the natural lens that was surgically removed, so that the elasticity of the capsule may serve more advantageously to exert inward radial force on the lens assembly as described below.

In a further alternative embodiment, expanding ring 24 may be eliminated, and linkage arms 22 may instead be rotatably coupled at their outer ends to anchors, which may be glued or sutured to capsule edge 18, zonules 28 or less preferably, ciliary muscle 34. More preferably, the expanding ring is not eliminated but is provided as a split ring so that it exerts no force of its own in the radial direction while preserving the lens capsule in an open condition.

In general, the axial position of the optic depends on the balance of forces between the zonules (and the expanding ring, if present) which urge edge 19 of the lens capsule outward and the resilience of the lens capsule which urges the edge of the lens capsule inward. The effect of the force of the posterior wall 19 of the lens capsule on the optic also tends to push edge 18 of the lens capsule, outward. In many embodiments of the invention the urging of the optic by the posterior wall enables the expanding ring 24 and the outer end position on the linkage arms to be held in place without any attachment

of the lens assembly to the lens capsule or to the zonules. This simplifies implantation considerably.

It may be appreciated that in preferred embodiments of the present invention, a wide variety of mechanical designs may be applied to the intraocular lens system and, more specifically, to linkage arms 22 and pivots 26 and 27, with the objective of increasing and otherwise controlling the axial displacement of optic 14 resulting from radial forces applied at the pivots.

Preferably, the ratio of axial to radial displacement is large enough to provide at least 5:1 amplification of the radial motion, so as to provide substantially complete accommodation. In saying this, it is understood that complete accommodation requires an axial movement of the optic 14 of approximately 1 mm while the maximum radial movement of the ciliary muscle 34 is approximately 200 micrometers. However, it will be appreciated that other ratios may be employed as required.

In particular, a larger ratio will result in a range of accommodation which is larger than required for near/far vision. When such larger accommodation ratios are available, the exact placement of the optic becomes less critical since the contraction of the ciliary muscle will be sufficient to provide full accommodation even if far vision is overcompensated when the ciliary muscle is relaxed.

Reference is now made specifically to Figs. 3A and 3B, which illustrate an intraocular lens system including an optic 54 and arms 62, each having a beam 64 and pivots 66 and 67. It is seen that Fig. 3A illustrates the intraocular lens system where a force is applied to arms 62 causing bending thereof about pivots 66 and 67 and rearward displacement of the optic 54. Fig. 3B illustrates the intraocular lens system of Fig. 3A in the absence of such force, where the arms 62 are generally unbent at pivots 66 and 67, thus placing the optic 54 forwardly of its position shown in Fig. 3A.

Figs. 3C and 3D illustrate an intraocular lens system constructed and operative according to another embodiment of the invention and including an optic 74 and arms 82, each having a beam 84 and pivots 86 and 87. It is seen that Fig. 3C illustrates the intraocular lens system where a force is applied to arms 82 causing bending thereof about pivots 86 and 87 and forward displacement of the optic 74. Fig. 3D illustrates the intraocular lens system of Fig. 3C in the absence of such force, where the

arms 82 are generally unbent at pivots 86 and 87, thus placing the optic 74 rearwardly of its position shown in Fig. 3C.

Reference is now made to Figs. 4, 5A, 5B and 6A - 6D, which illustrate an alternative embodiment of the present invention. This embodiment is similar to the embodiment of Figs. 1 - 3D described hereinabove with the difference between the embodiments being that in the embodiment of Figs. 4 - 6D the beam is much longer than the beam in the embodiment of Figs. 1 - 3D The pivots may or may not be shorter than the pivots in the embodiment of Figs. 1 - 3D. Due to the increased length of the beam in the embodiments of Figs. 4 - 6D, the pivots are located relative to the optic and to the ring at locations different from those in the embodiment of Figs. 1 - 3D.

Fig. 4 shows a cross-section of a human eye 110 having an adaptive intraocular lens system 112, in accordance with a preferred embodiment of the invention, installed in place of the original material in a lens capsule 116. In this and all other cross-sectional diagrams of the eye and structures therein, the cornea and other anterior portions of the eye are at the left of the figure, and the retina and posterior portions of the eye are to the right.

Intraocular lens system 112 comprises an optic 114 placed within lens capsule 116. Lens capsule 116, from which the original lens material has been removed, includes an outer edge 118, which is left intact and, optionally, a posterior wall 119 at least a portion of which may be left intact. At least a portion of the original anterior wall of the capsule is generally removed during the operation for removal of the lens material leaving an opening 120, through which the lens system is installed.

As shown more clearly in Figs. 5A, 5B, and 6A - 6D, intraocular lens system 112 also includes two or more linkage arms 122, also known as haptics, which are integrally formed as one piece with the optic 114 at one end of the arms and which preferably rest on or are pivotably attached to an expanding ring 124 at a second end thereof. In the embodiment of Figs. 4, 5A, 5B and 6A - 6D, as seen most clearly in Fig. 5A, the linkage arms 122 generally surround the optic 114 and are attached thereto at the sides of the optic.

In a preferred embodiment of the invention shown in Figs. 4 - 6D, arms 122 are pivotably attached for limited rotational motion at pivots 126, symmetrically

placed on the outer edge of the optic 114, and at pivots 127 on expanding ring 124. In accordance with a preferred embodiment of the present invention, pivots 126 and 127 are defined by flexible sections of the integrally formed one-piece intraocular lens system.

As shown in Fig. 4, one end of zonular fibers 128, also known as zonules, is attached to edge 118 of lens capsule 116. The other end of the zonules is attached to the sclera 130 of the eye. Intermediate their ends, the zonular fibers are acted upon by ligaments or the like 132 which are controlled by ciliary muscle 134. The portion of the eye comprising the ciliary muscle and the volume it encloses is also known as the ciliary body.

Optic 114 produces an image on the retina at the back of the eye 110 corresponding to a focal plane 136. In order to provide accommodation, optic 114 is made capable of movement along optical axis 138. As in the normal eye, accommodation is made consequent to changes in tension of the zonular fibers. This change in tension acts on optic 114 so as to alter the image distance from optic 114 to focal plane 136.

In the preferred embodiment shown in Figs. 5A and 5B, linkage arms 122 each include a central beam portion 140, which is relatively rigid, having formed onto opposite ends thereof pivots 126 and 127. In contrast to the prior art, which employs different materials for the optic and the arms 122, the present invention may employ the same material for optic 114 and for arms 122, including the beam portion 140 and the pivots 126 and 127, wherein the relative rigidity of each portion is determined by its thickness.

Alternatively the intraocular lens system may be formed as one piece from plural materials or reinforced, so as to cause various portions thereof to have greater or lesser rigidity.

The pivots 126 and 127 may be made of flexible material, which allows twisting or rotation of the arms about the pivot in response to rotational force applied to the arms 122, but prevents substantial axial motion of the arms. This flexible material may also be elastic, so that pivots 126 and 127 exert a biasing force on arms 122, which will tend to return optic 114 to its original position when the rotational force applied to the arms is removed.

Expanding ring 124 is constructed preferably so as to exert an outward radial force, which will cause the ring to conform to the edge 118 of lens capsule 116, and expand or contract in response to expansion or contraction of the capsule, respectively. Ring 124 serves to couple the outer end of linkage arms 122 to edge 118, so that radial forces exerted by zonules 128 and ciliary muscle 134 can act upon the arms.

Ring 124 may further serve to open capsule 116, i.e., to separate the anterior and posterior portions of the lens capsule, in place of the natural lens that was surgically removed, so that the elasticity of the capsule may serve more advantageously to exert inward radial force on the lens assembly as described below.

In a further alternative embodiment, expanding ring 124 may be eliminated, and linkage arms 122 may instead be rotatably coupled at their outer ends to anchors, which may be glued or sutured to capsule edge 118, zonules 128 or less preferably, ciliary muscle 134. More preferably, the expanding ring is not eliminated but is provided as a split ring so that it exerts no force of its own in the radial direction while preserving the lens capsule in an open condition.

In general, the axial position of the optic depends on the balance of forces between the zonules (and the expanding ring, if present) which urge edge 118 of the lens capsule outward and the resilience of the lens capsule which urges the edge of the lens capsule inward. The effect of the force of the posterior wall 119 of the lens capsule on the optic also tends to push edge 118 of the lens capsule, outward.

In many embodiments of the invention the urging of the optic by the posterior wall enables the expanding ring 124 and the outer end position on the linkage arms to be held in place without any attachment of the lens assembly to the lens capsule or to the zonules. This simplifies implantation considerably.

It may be appreciated that in preferred embodiments of the present invention, a wide variety of mechanical designs may be applied to the intraocular lens system and, more specifically, to linkage arms 122 and pivots 126 and 127, with the objective of increasing and otherwise controlling the axial displacement of optic 114 resulting from radial forces applied at the pivots.

Reference is now made specifically to Figs. 6A and 6B, which illustrate an intraocular lens system including an optic 154 and arms 162, each having a beam 164 and pivots 166 and 167. It is seen that Fig. 6A illustrates the intraocular lens system where a force is applied to arms 162 causing bending thereof about pivots 166 and 167 and rearward displacement of the optic 154. Fig. 6B illustrates the intraocular lens system of Fig. 6A in the absence of such force, where the arms 162 are generally unbent at pivots 166 and 167, thus placing the optic 154 forwardly of its position shown in Fig. 6A.

Figs. 6C and 6D illustrate an intraocular lens system constructed and operative according to another embodiment of the invention and including an optic 174 and arms 182, each having a beam 184 and pivots 186 and 187. It is seen that Fig. 6C illustrates the intraocular lens system where a force is applied to arms 182 causing bending thereof about pivots 186 and 187 and forward displacement of the optic 174. Fig. 6D illustrates the intraocular lens system of Fig. 6C in the absence of such force, where the arms 182 are generally unbent at pivots 186 and 187, thus placing the optic 174 rearwardly of its position shown in Fig. 6C.

Reference is now made to Fig. 6E which illustrates the principle of operation of the integrally formed once piece intraocular lens system of the present invention. It is seen that the pivots 186 and 187 are off-axis with respect to the axis of a force applied to the intraocular lens system along an axis 244, as illustrated by arrows 246. Thus application of the force along axis 244 as indicated by arrows 246, causes displacement of an optic 174 in a direction indicated by an arrow 250 directed in the off-axis direction.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the features described hereinabove as well as variations and modifications thereof which would occur to a person of skill in the art upon reading the foregoing description, and which are not in the prior art.

I CLAIM:

1. An intraocular lens assembly for implantation in a human eye, the eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly including:

an optic having anterior and posterior surfaces;

at least two articulated linkage arms, each being attached to the optic at a first position on the arm thereof and cooperating with the ciliary muscle or the zonules at a second position on the arm, the optic being integrally formed as a single piece together with the at least two articulated linkage arms.

2. An intraocular lens assembly according to claim 1 and also comprising a ring attached to the at least two articulated linkage arms and integrally formed therewith as a single piece.

3. An intraocular lens assembly according to claim 1 or claim 2 and also comprising at least two pivots, one of which is rotatably attached to each respective linkage arm intermediate the first and second positions.

4. An intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly comprising:

an optic having anterior and posterior surfaces;

at least two linkage arms, each being integrally formed as one piece with said optic at a first position on the arm thereof and cooperating with ciliary muscle or the zonules at a second position on the arm; and

at least two pivots, one of which is rotatably attached to each respective linkage arm intermediate the first and second positions.

5. An intraocular lens assembly according to claim 4 wherein the assembly is adjusted so that when the ciliary muscle is relaxed, the optic is located at a

predetermined distance from the rear surface of the eye for correct far vision, and wherein contraction of the ciliary muscle causes a radial motion of an edge of the lens capsule, causing the linkage arms to rotate about said pivots so as to axially displace the optic away from the rear surface of the eye.

6. An intraocular lens assembly according to any of claims 4 and 5, wherein the linkage arms and pivots are so arranged that said radial movement of second position of the linkage arms causes the optic to move axially by a distance substantially greater than the distance of said radial movement.

7. An intraocular lens assembly according to any of claims 4 - 6 and comprising a generally rigid ring having a diameter greater than that of the optic and wherein the lever arms and the rigid ring are attached at said pivots.

8. An intraocular lens assembly according to claim 7 wherein the pivots comprise flexible portions in said otherwise rigid ring.

9. An intraocular lens assembly according to claim 8, wherein:

the ring is formed of at least two rigid sections interconnected by a biologically inert sleeve so as to allow twisting of respective portions of the sleeve intermediate the rigid sections, and

said respective portions of the sleeve serve as fulcrums.

10. An intraocular lens assembly according to claim 8 or claim 9, wherein said ring is provided with one or more initial kinks which can be at least partially straightened during implantation of the lens assembly in order to adjust the distance of the optic from the rear surface of the eye to said predetermined distance.

11. An intraocular lens assembly according to any claims 4 - 10, wherein at least two optics are commonly coupled to the respective linkage arms at the pivots.

12. An intraocular lens assembly according to any of the preceding claims wherein the linkage arms are rigid except at flexible joints.

13. An intraocular lens assembly according to any of the preceding claims, wherein a resilient bias operates on each of said linkage arms to maintain the optic at the desired distance from the rear surface of the eye, in response to radial movement of said second position.

14. An intraocular lens assembly according to any of the preceding claims wherein the eye also includes at least a portion of a lens capsule including at least a peripheral edge thereof attached to the zonules and wherein the resilient bias is at least partially provided by the edge.

15. An intraocular lens assembly according to claim 14 wherein the lens capsule also includes at least a portion of the posterior wall thereof and wherein the resilient bias is at least partially provided by the posterior wall.

16. An intraocular lens assembly according to claim 15, wherein the resilient bias is at least partially provided by stretching of the posterior capsule wall attached to the ciliary muscle at opposing extremities of the lens capsule, and

the assembly is adjusted so that, when the ciliary muscle is relaxed, the optic is located against the posterior capsule wall.

17. An intraocular lens assembly according to claim 15 or claim 16 and including and including an expanding ring associated with the edge which contacts the edge portion of the lens capsule and positions the posterior wall toward the back of the eye and away from the center of the lens capsule.

18. An intraocular lens assembly according to any of claims 1 - 13 wherein the eye includes at least a portion of a lens capsule including at least a peripheral edge

thereof attached to the zonules and wherein the linkage arms cooperate with the edge of the lens capsule.

19. An intraocular lens assembly according to claim 18 wherein the portion of the lens capsule includes at least a portion of the posterior wall and including an expanding ring associated with the edge which contacts the edge portion of the lens capsule and positions the posterior wall toward the back of the eye and away from the center of the lens capsule.

20. An intraocular lens according to any of the preceding claims wherein the tension of the zonules causes the second position of the linkage arms to move outward.

21. An intraocular lens assembly according to any of claims 1 - 20 wherein the tension of the zonules causes the second position of the linkage arms to move inward.

22. An intraocular lens assembly according to any of the preceding claims, wherein at least one of the linkage arms is attached to the zonules or the ciliary muscle at the first position of the respective linkage arm.

23. An intraocular lens assembly according to any of the preceding claims, wherein the respective linkage arms are attached to an edge of the optic.

24. An intraocular lens assembly according to claim 23 wherein the attachment at the edge of the lens comprises attachment of the linkage arms along the edge of the optic by a flexible coupling which allows for rotation of the linkage arm with respect to the edge of the optic.

25. An intraocular lens assembly according to any of claims 1 - 24 wherein the respective linkage arms are attached to a face of the optic.

26. An intraocular lens assembly according to any of the preceding claims, wherein at least a portion of the linkage arms is provided with one or more initial kinks which can be at least partially straightened during implantation of the lens assembly in order to adjust the distance of the optic from the rear surface of the eye to said predetermined distance.

27. An intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle and at least a portion of a lens capsule including an edge thereof and at least a portion of a posterior wall thereof, the assembly comprising:

an expanding ring associated with the edge which contacts the edge portion of the lens capsule and positions the posterior wall toward the back of the eye from center of the lens capsule; and

an optic associated with the expanding ring and integrally formed therewith as a single piece.

28. An intraocular lens assembly according to any of claims 15 - 19 wherein the edge also bears against the posterior wall to further position the wall toward the back of the eye.

29. An intraocular lens assembly according to either of claims 17 and 19 and wherein the expanding ring also provides a resilient radial force on the edge.

30. An intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle and at least a portion of a lens capsule including an edge thereof, the assembly comprising:

an expanding ring associated with the edge portion of the lens capsule and which provides a resilient radial force on the edge; and

an optic associated with the expanding ring and integrally formed therewith as one piece.

31. An intraocular lens assembly according to claim 28 or claim 29 wherein the expanding ring bears against the edge and provides an outwardly directed radial force on the edge.

32. An intraocular lens assembly according to claim 28 or claim 29 wherein the expanding ring is attached to the edge and provides an inwardly directed radial force on the edge.

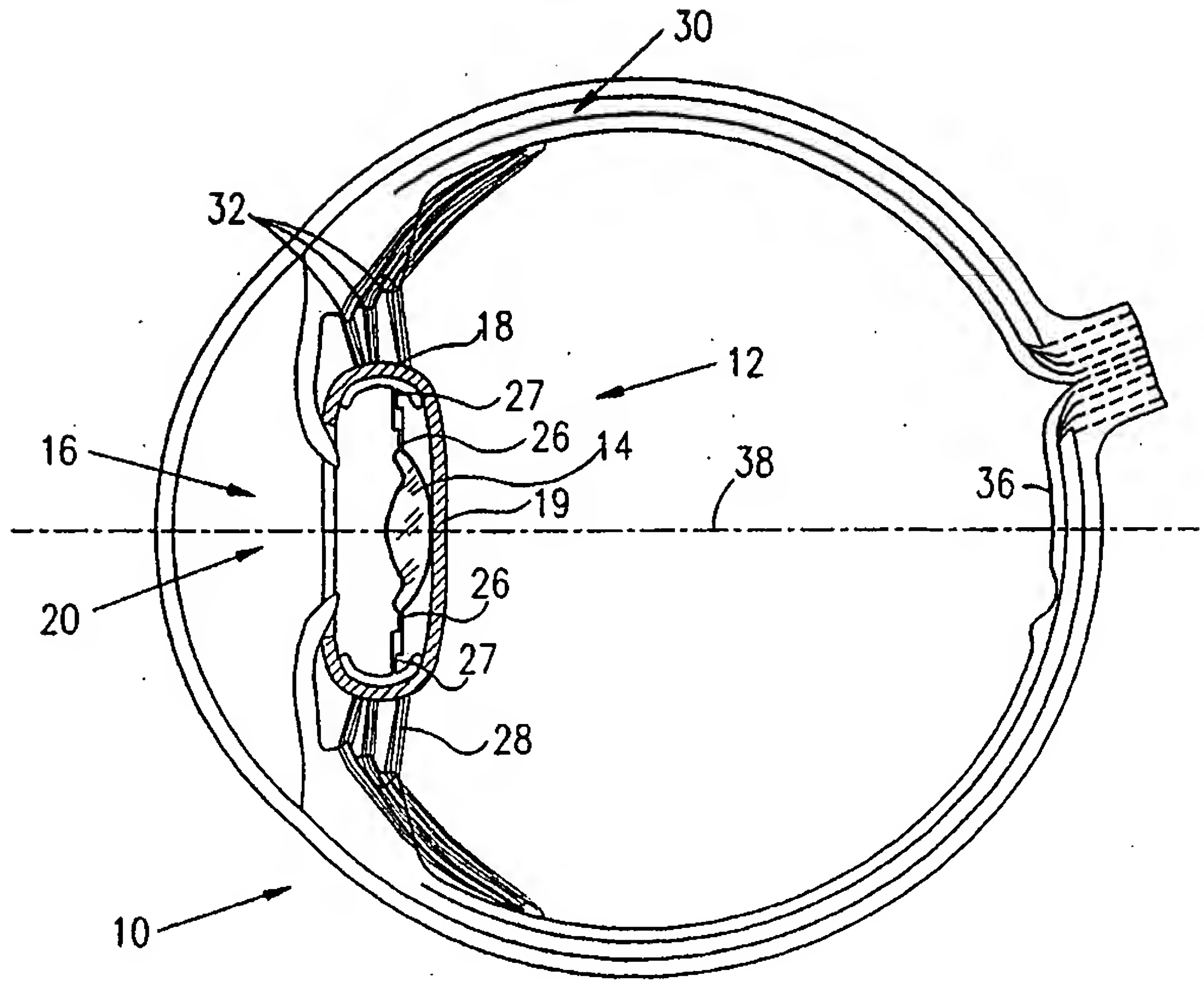

FIG. 1

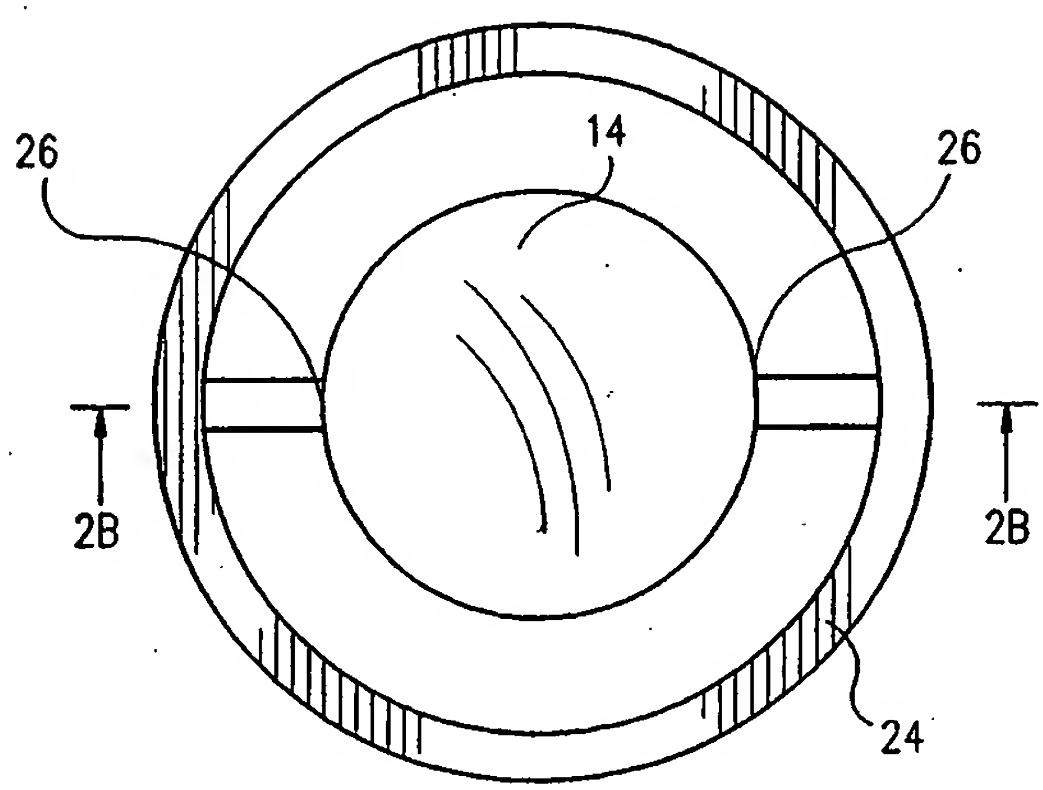

FIG. 2A

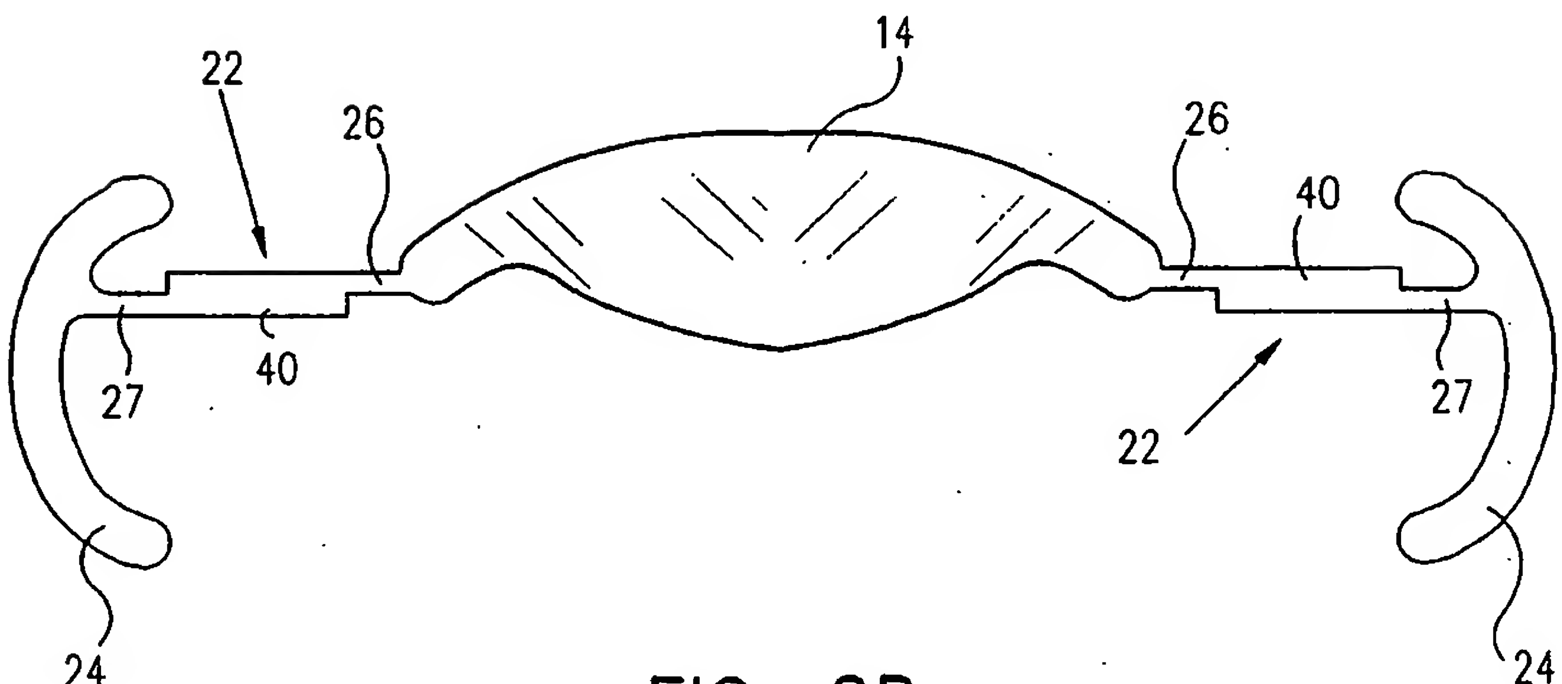

FIG. 2B

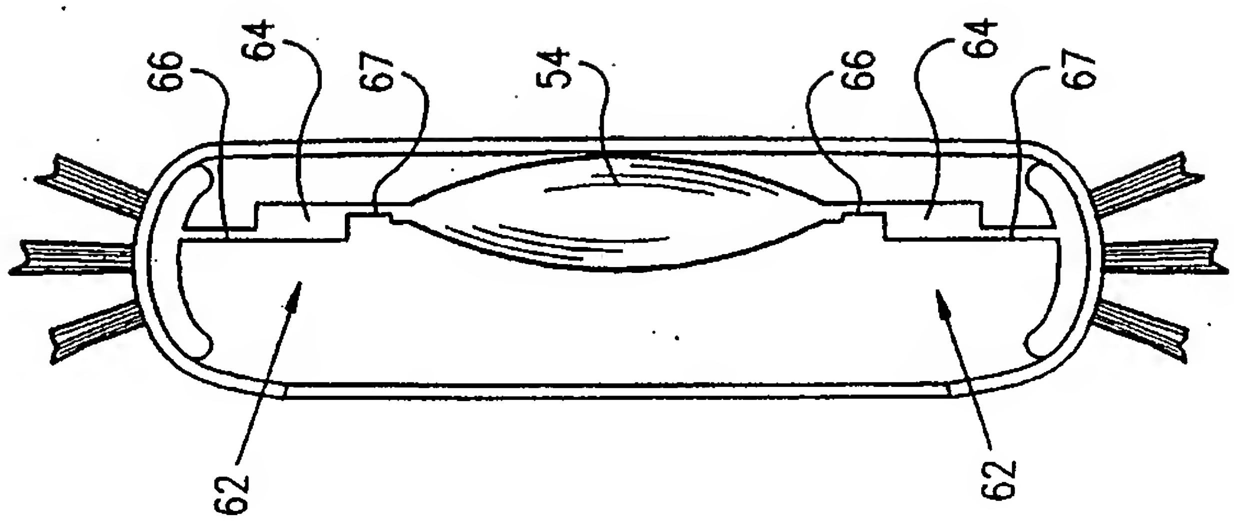

FIG. 3B

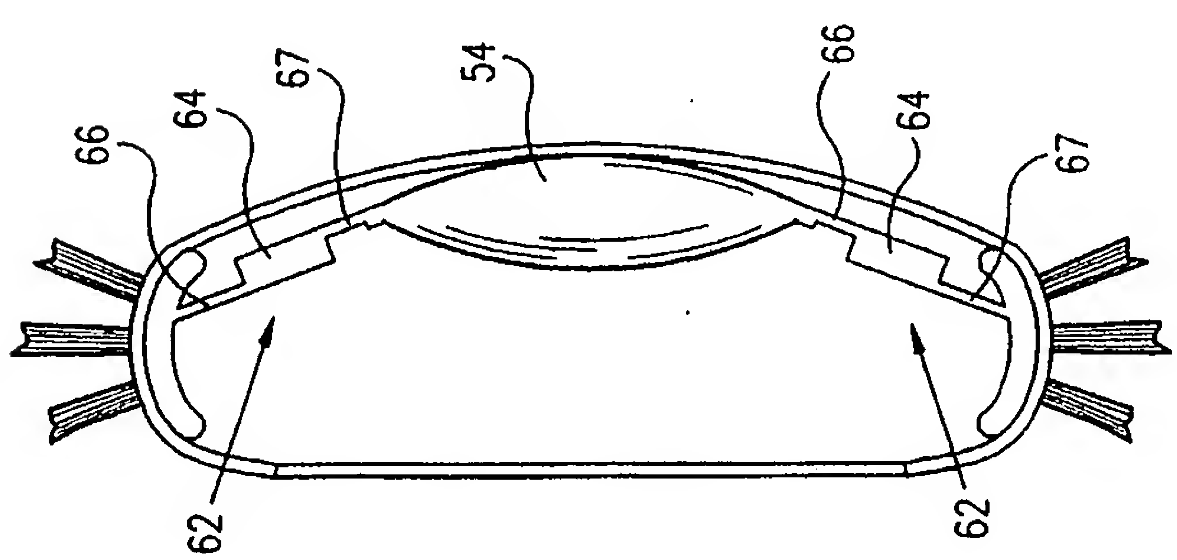

FIG. 3A

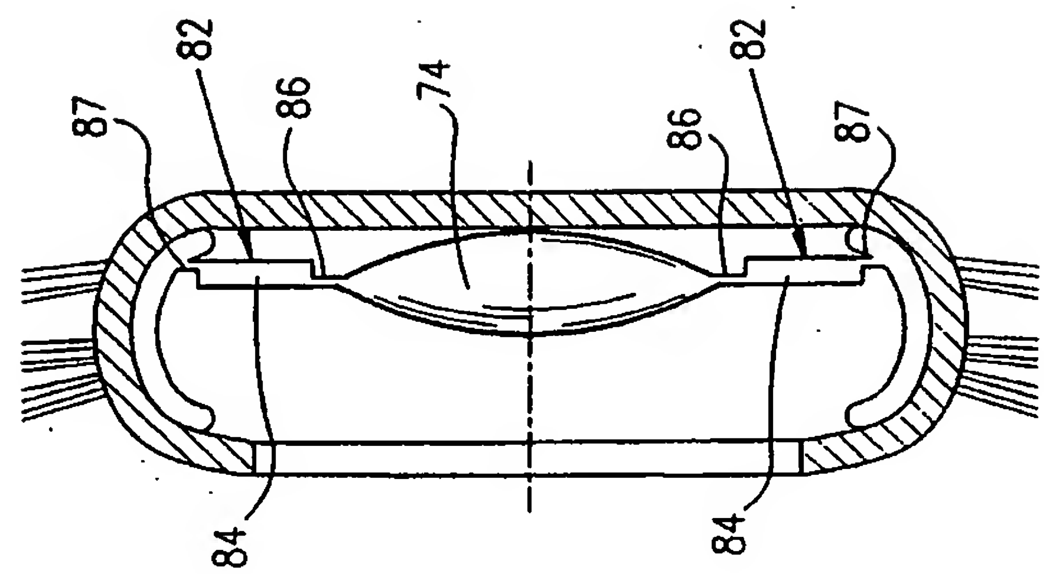

FIG. 3D

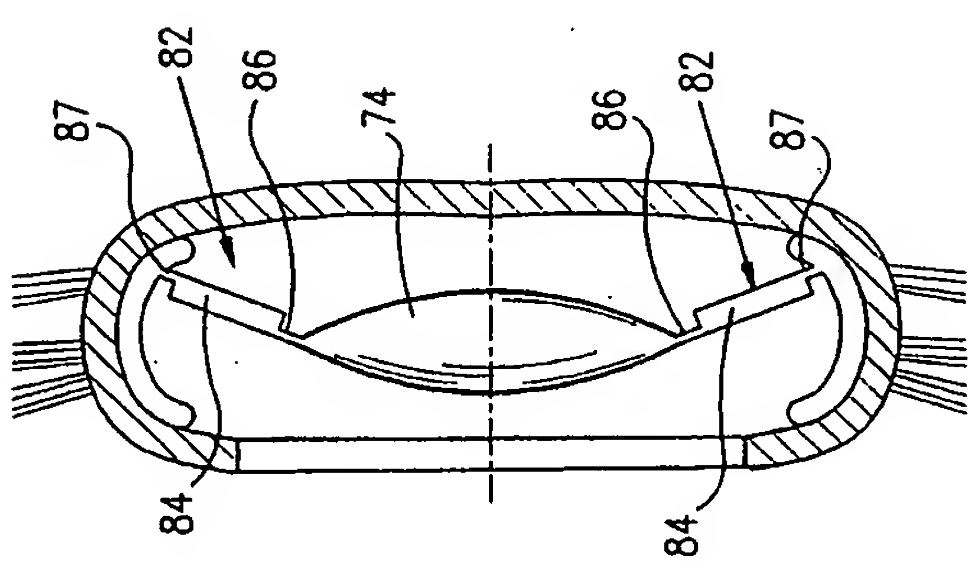

FIG. 3C

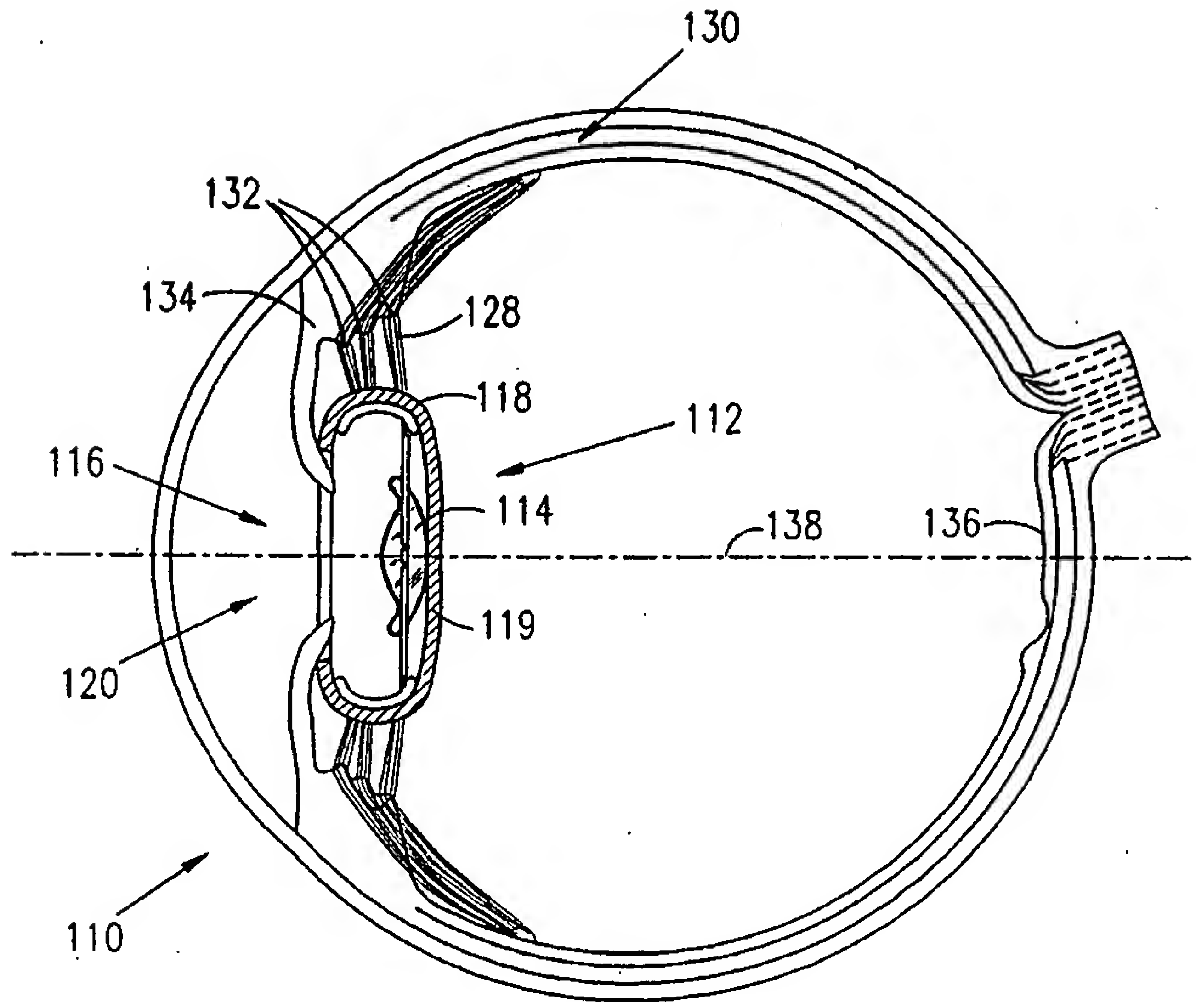

FIG. 4

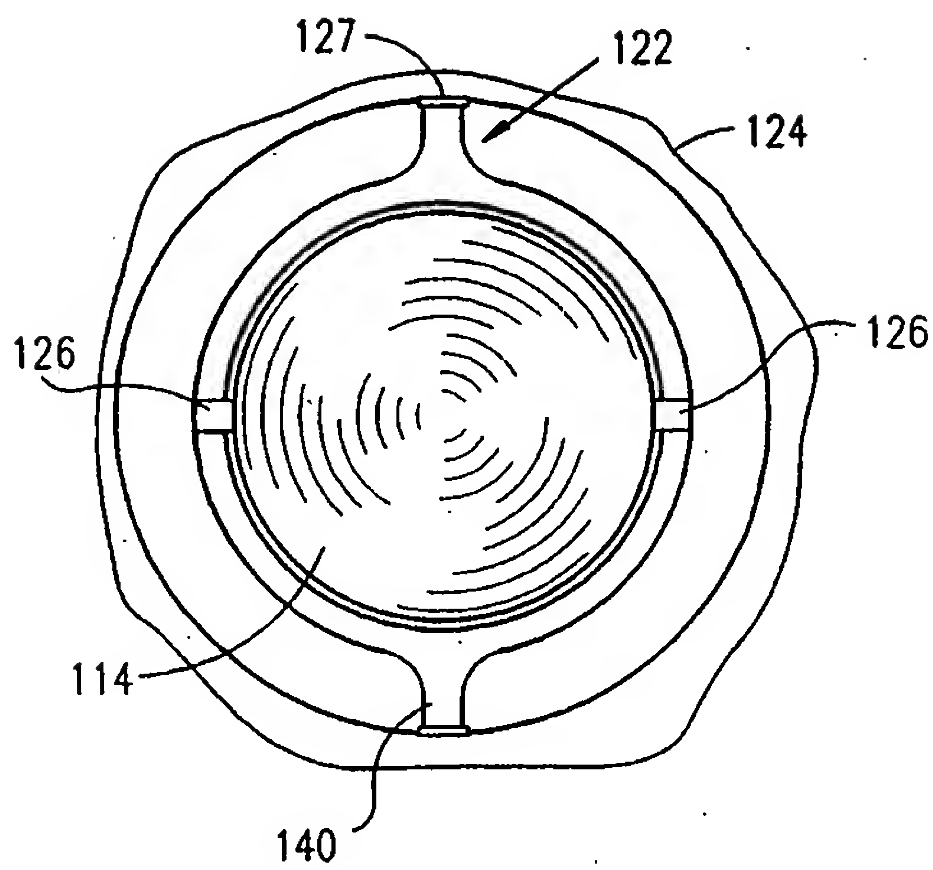

FIG. 5A

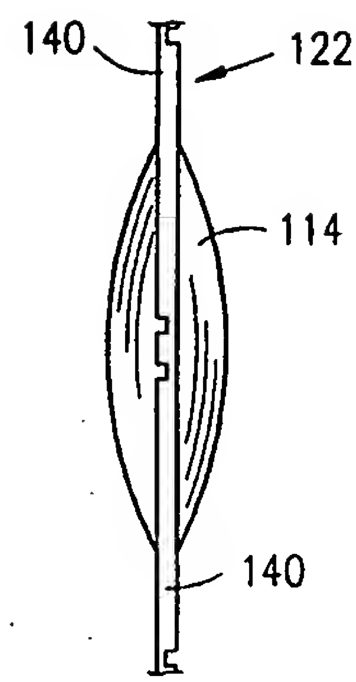

FIG. 5B

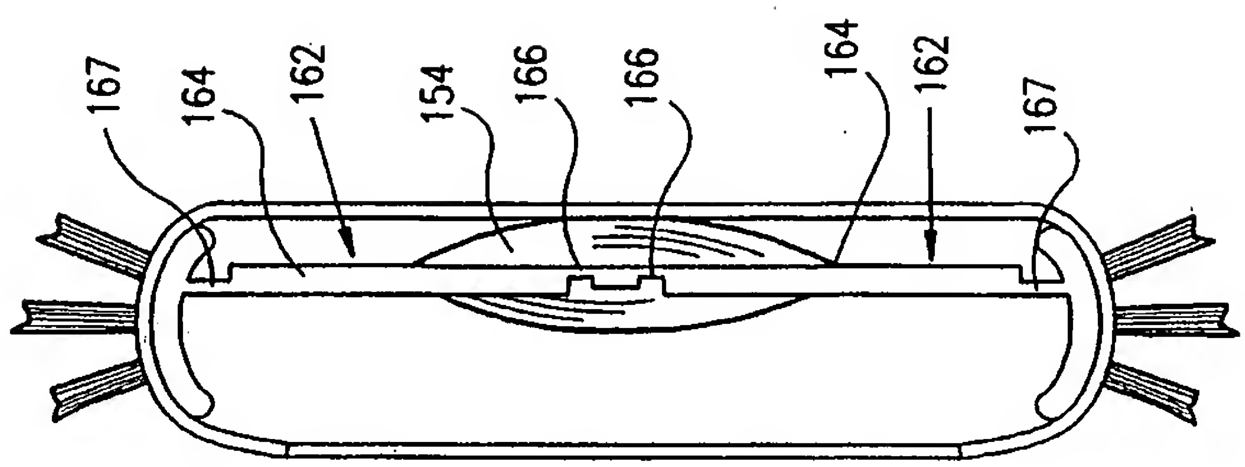
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FIG. 6B

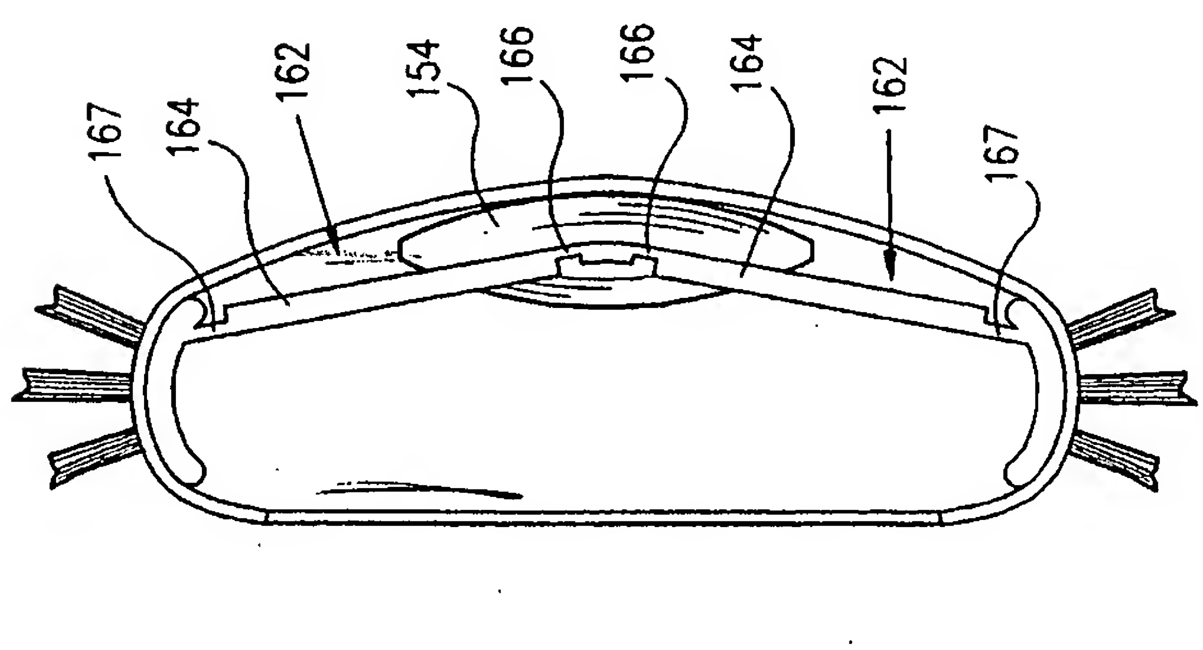
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FIG. 6A

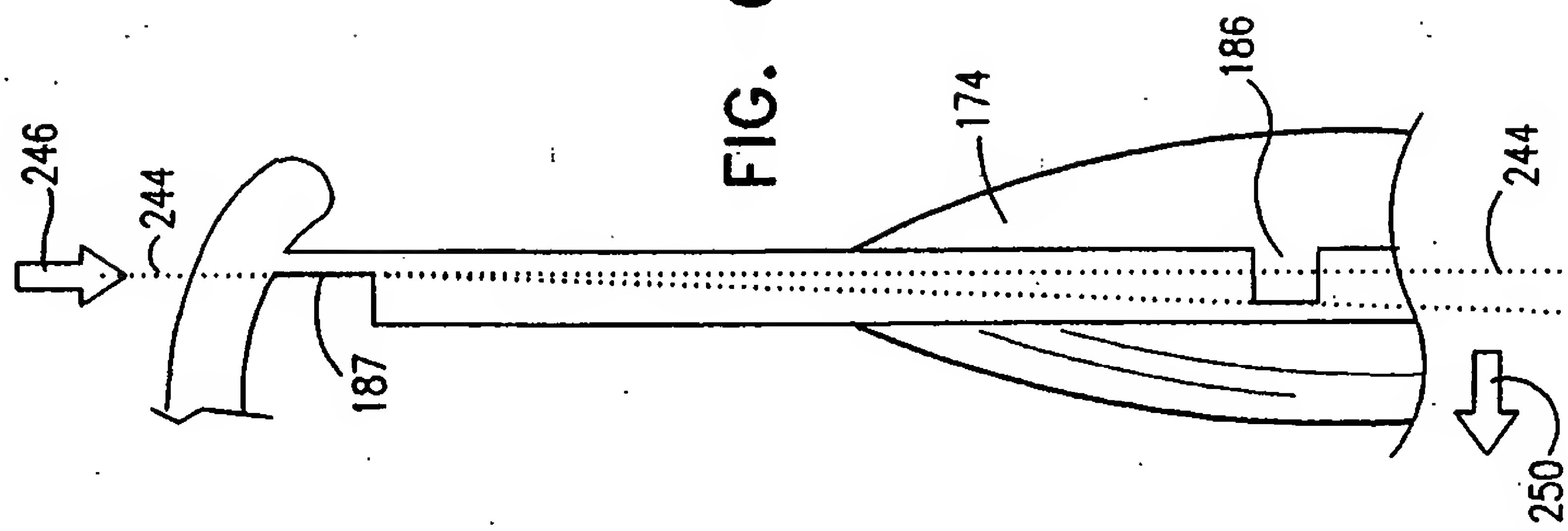

FIG. 6E

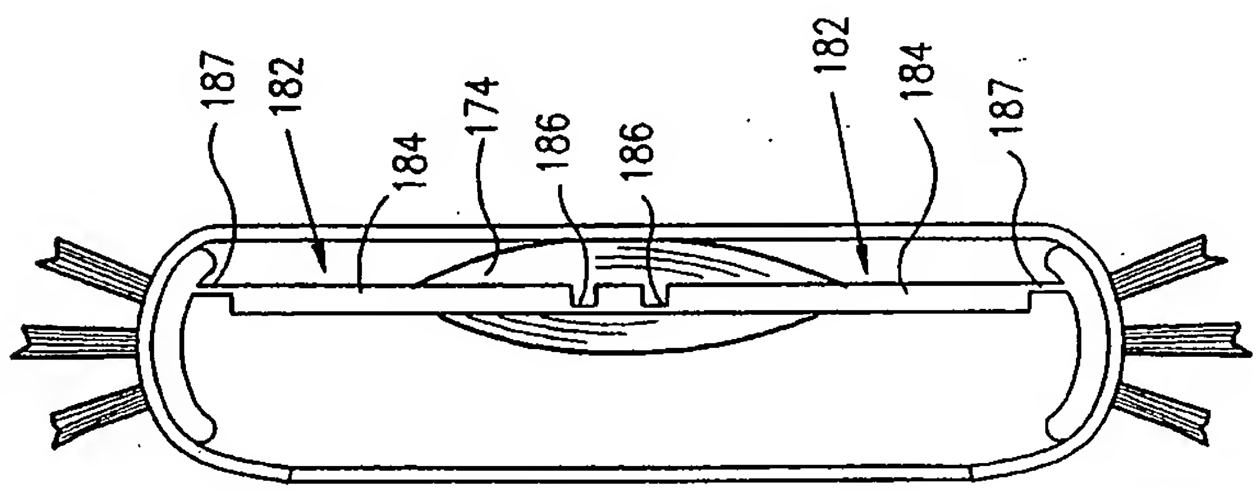

FIG. 6D

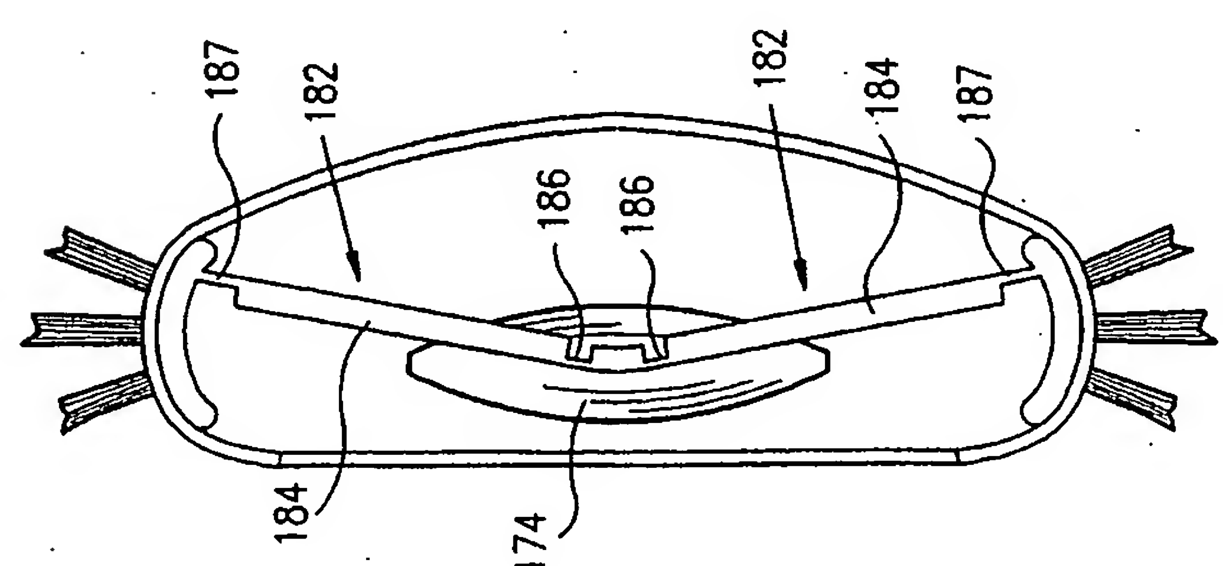

FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00337

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/16
US CL :623/6
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS
Search Terms: 623/6/cols and accommoda?

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,790,847 A (WOODS) 13 December 1988, the entire document.	1, 3-6
X	US 5,476,514 A (CUMMING) 19 December 1995, entire document especially Figs. 19, 20 and 22-24.	1-4, 6, 29
X	US 4,409,691 A (LEVY) 18 October 1983, entire document.	1, 3-6, 29
X	US 4,254,509 A (TENNANT) 10 March 1981, entire document.	1, 3-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 OCTOBER 1998	18 DEC 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
PAUL PREBILIC
Telephone No. (703) 308-2905

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00337

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 7-28, 30-31
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.